

### **Remarks**

Applicants appreciate the Examiner's telephone call on June 9, 2005, during which the typographical errors in the Office Action dated May 23, 2005 were discussed and corrected. The correction was evinced in an Interview Summary of June 14, 2005 written by the Examiner, in which the first sentence of item 5 at page 2 is rewritten as follows:

“Claims 13-15 and 58-60 are rejected under 35 U.S.C. § 102(e) as being anticipated by Morgan (U.S. 6274579, 6391875, 2003/0064988).”

Claims 13-15 and 58-77 are pending in this application. New claims 61-77 are added. These new claims are supported by the specification, for example, at page 15, lines 24-29; at page 16, line 29 to page 17, line 8; at page 5, line 15 to page 6, line 7; at page 7, lines 7-11; and at page 2, lines 11-18.

Claims 15, 58, and 60 are amended to correct typographical errors by replacing each of the terms “morphinol” with “morpholinol.” The amendments are supported by the specification, for example, at page 2, line 3; and at page 5, lines 1-14.

No new matter has been introduced by the above-mentioned amendments. Applicants respectfully submit that the pending claims are allowable at least for the following reasons.

#### **A. The Rejection Under 35 U.S.C. § 102(e) Should Be Withdrawn**

In the Office Action, claims 13-15 and 58-60 are rejected under 35 U.S.C. § 102(e) as being anticipated by a series of Morgan references (U.S. Patent No. 6,274,579 (“the ‘579 patent”); U.S. Patent No. 6,391,875 (“the ‘875 patent”); U.S. Patent Publication No. 2003/0064988 (“the ‘988 publication”)). In particular, it is alleged that: 1) the treatment of weight gain, attention deficit disorder (ADD), and seasonal affective disorder as recited by claim 13 are “corresponding to” the treatment of obesity, ADHD, and depression, respectively, as allegedly disclosed in the ‘579 patent; and 2) the treatment of nicotine addiction with (2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol as recited by claim 60 is allegedly disclosed in the ‘579 patent (Office Action, page 3). Applicants respectfully traverse this rejection.

In order to anticipate a claim, the cited reference(s) must disclose each and every limitation of the claim. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California,*

814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully point out that the ‘579 patent does not disclose each and every limitation of claim 13.

Claim 13 recites, in part, the treatment or prevention of seasonal affective disorder.<sup>1</sup> However, contrary to the Examiner’s contention, seasonal affective disorder is not “corresponding to” depression as allegedly disclosed in the ‘579 patent.

Mood or affective disorders are a group of heterogeneous, typically recurrent, illnesses including unipolar (depressive) and bipolar (manic-depressive) disorders. (See *The Merck Manual of Diagnosis and Therapy*, 17<sup>th</sup> Edition, 1999, 1525-1539 at 1525, attached hereto as Exhibit 1). Mood or affective disorders have various causes and symptoms. (See *id.* at pages 1527 and 1529). Further, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) describes seasonal affective disorder (SAD) as a seasonal pattern of depressive episodes that can occur within major depressive and bipolar disorders. (See DSM-IV, 1994, 425-427, attached hereto as Exhibit 2). DSM-IV states that it is unclear “whether a seasonal pattern is more likely in Major depressive Disorder, Recurrent, or in Bipolar Disorders.” (*Id.* at page 426). Therefore, these references make it clear that causes and classification of SAD are not well established, but that SAD is a distinct type of disorder.

Furthermore, it has been reported that the treatment options for SAD are not necessarily the same as those for general depression. (See Saeed *et al.*, American Family Physician, 57(6), downloaded from [www.aagp.org/afp/980315ap/saeed.html](http://www.aagp.org/afp/980315ap/saeed.html) (1998) (“Saeed”), attached hereto as Exhibit 3). Saeed suggests that, although debatable, SAD may be a syndrome distinct from depression because treatments that have no effect on general depression have been reported to be effective in certain SAD patient population. (*Id.*, pages 3-4).

Based on these facts, Applicants respectfully point out that SAD is a disorder distinct from depression, which may involve different treatment options than depression. Furthermore, even assuming, *arguendo*, that SAD is not completely different, it is at most merely a subgenus or species of depression or bipolar disorders, and thus the treatment of depression as disclosed generally in the ‘579 patent cannot anticipate the treatment of SAD as recited by claim 13.

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<sup>1</sup> Although Applicants respectfully disagree with the Examiner’s contention, claim 13 is amended to remove the recitation of “ADD” and “weight gain” solely to expedite the prosecution of this application.

Despite this fact, the Examiner cites to col. 2, paragraph 20 of the '643 publication in support of the allegation that depression is "corresponding to" SAD. It should be noted, however, that the '643 publication was filed February 13, 2003 as a CIP of the '875 patent. Further, the disclosure of the "treatment of seasonal affective disorder" is matter that was added for the first time in the '643 publication, and therefore it does not benefit from the priority date of its parent application. Therefore, Applicants respectfully point out that the '643 publication cannot constitute prior art to this application with regard to "seasonal affective disorder."

In addition, the portion of the '643 publication referred to by the Examiner states that the term "treatment of seasonal affective disorder" includes the treatment of major depressive disorder with seasonal pattern. Such a statement precisely shows that the treatment of SAD does not merely constitute the treatment of depression. Consequently, Applicants respectfully request that the rejection of claim 13 under 35 U.S.C. § 102(e) be withdrawn.

Applicants also submit that claim 60 is not anticipated by the '579 patent. This is because, while claim 60 recites, in part, the treatment or prevention of "nicotine addiction," the '579 patent discloses the treatment of "addiction to tobacco product." Nicotine (*i.e.*, 3-(1-Methyl-2-pyrrolidinyl)pyridine) is a chemical compound having a formula of  $C_{10}H_{14}N_2$ . Tobacco products, *albeit* they may contain nicotine, are not the same as nicotine itself. Therefore, Applicants respectfully submit that claim 60 is not anticipated by the '579 patent because it does not disclose each and every limitation of claim 60, in particular, the treatment or prevention of nicotine addiction. Consequently, Applicants respectfully request that the rejection of claim 60 under 35 U.S.C. § 102(e) be withdrawn.

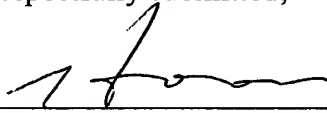
### **Conclusion**

For the foregoing reasons, Applicants respectfully submit that all of the pending claims are in allowable condition, and thus request that the rejection of the pending claims be withdrawn.

No fee is believed due for this submission. Should any fees be due for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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Attachments